

EPA REGISTRATION NUMBER 89110-3
VOLUME 1

PROCESSING REQUEST

Reg # 89110-3

Decision # 521473

Description: New product

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 11/29/16

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: Basic 9/13/16
A41 10/14/16

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: A. Heffernan

Division: AD

Phone: 347-8602

Date: 11/29/16



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

89110-3

Date of Issuance:

11/29/16

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Bionix GA50M

Name and Address of Registrant (include ZIP Code):

Isomeric Industries
361 17th Street NY #1224
Atlanta, GA 30363

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
Regulatory Management Branch I, Antimicrobials Division (7510P)

Date:

11/29/16

2. You are required to comply with the data requirements described in the DCI identified below:

a. Glutaraldehyde GDCI-043901-30859

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>.

3. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, "EPA Reg. No. 89110-3."

4. Submit one copy of the final printed label for the record before you release the product for shipment.

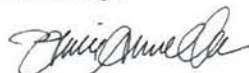
Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated September 13, 2016
- Alternate CSF 1 dated October 14, 2016

If you have any questions, you may contact Aline Heffernan at 703-347-8602 or via email at heffernan.aline@epa.gov.

Sincerely,



Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

BIONIX GA50M

FOR MANUFACTURING USE ONLY. FOR FORMULATING INDUSTRIAL BACTERICIDES AND PRESERVATIVES. FORMULATORS USING THIS PRODUCT ARE RESPONSIBLE FOR PROVIDING DATA FOR THE EPA REGISTRATION OF THEIR FORMULATED PRODUCTS.

Active Ingredient:

Glutaraldehyde: 50.0%

Other Ingredients: 50.0%

Total: 100.0%

EPA Reg. No. 89110-TBD EPA Est. **NET CONTENTS:** As Marked on Container

KEEP OUT OF REACH OF CHILDREN DANGER

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
If on skin or clothing:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
If swallowed:	<ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person.
If inhaled:	<ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.• Call a poison control center for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	
Note to physician: Aspiration may cause lung damage. Probable mucosal damage may contraindicate the use of gastric lavage.	

[See side panels for additional Precautionary Statements]

In case of emergency, call INFOTRAC: (800)-535-5053

Manufactured for:
ISOMERIC INDUSTRIES
361 17TH Street NW #1224
Atlanta, GA 30363
678-665-4275

ACCEPTED

Nov 29, 2016

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 89110-3

Bionix GA50M (89110-TBD)

Isomeric Industries

A530 - September 13, 2016, Label Version (4), November 3, 2016

Page 1 of 4

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER. Corrosive. Causes irreversible eye damage. Causes skin burns. May be fatal if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Causes asthmatic signs and symptoms in hyper-reactive individuals. Do not get in eyes, on skin, on clothing. Avoid breathing vapor. Do not swallow. Wear goggles, protective clothing, and butyl or nitrile gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove contaminated clothing and wash before reuse.

User Safety Recommendations

BEFORE HANDLING OR USING THIS PRODUCT, SEE YOUR EMPLOYER AND READ THE CURRENT SAFETY DATA SHEET. Users must remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must wash hands before eating, drinking, chewing gum, or using the toilet. Users must remove PPE immediately after handling this product. Wash outside of gloves before removing. As soon as possible, wash thoroughly. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS:

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, ponds, streams, estuaries, oceans, or public water unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

FOR FORMULATION OF INDUSTRIAL BACTERICIDES AND PRESERVATIVES FOR USE IN:

- AIR WASHERS AND INDUSTRIAL SCRUBBING SYSTEMS, RECIRCULATING COOLING AND PROCESS WATER SYSTEMS INCLUDING THOSE THAT CONTAIN REVERSE OSMOSIS MEMBRANES, SERVICE WATER AND AUXILIARY SYSTEMS, HEAT TRANSFER SYSTEMS, WASTEWATER SYSTEMS INCLUDING WASTEWATER SLUDGE AND HOLDING TANKS.
- BEET SUGAR MILLS AND BEET SUGAR MILL PROCESS WATER SYSTEMS.
- PAPER MILLS AND PAPER MILL PROCESS WATER SYSTEMS, PIGMENTS AND FILLER SLURRIES FOR PAPER AND PAPERBOARD, WATER BASED COATINGS FOR PAPER AND PAPERBOARD
- WATER BASED CONVEYOR LUBRICANTS AND AQUEOUS METALWORKING FLUIDS AND IN INDUSTRIAL, INSTITUTIONAL AND CONSUMER PROCESSES AND PRODUCTS IN AQUEOUS-BASED SOLUTIONS, SLURRIES AND EMULSIONS.
- OIL WELL DRILLING, OIL FIELD PROCESSING APPLICATIONS, OIL FIELD WATER SYSTEMS, GAS PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS AND GAS STORAGE FIELDS AND EQUIPMENT SUCH AS STEAM INJECTION WATER HOLDING TANKS, FLOOD WATER, INJECTION WATER, HOLDING POND WATER, DISPOSAL-WELL WATER, WATER HOLDING TANKS, FUEL STORAGE TANKS AND RELATED REFINERY AND OIL FIELD CLOSED, INDUSTRIAL RECIRCULATING WATER HANDLING SYSTEMS.

Bionix GA50M (89110-TBD)

Isomeric Industries

A530 - September 13, 2016, Label Version (4), November 3, 2016

Page 2 of 4

- NON-FOOD CONTACT SURFACES OF ANIMAL PRODUCTION FACILITIES AND FARM EQUIPMENT SUCH AS: POULTRY & TURKEY HOUSES, SWINE HOUSING AND FARROWING AREAS, BARNs AND LARGE ANIMAL BUILDINGS, HATCHERS, SETTERS AND CHICK PROCESSING FACILITIES, CAGES AND TRANSPORT VEHICLES, AND FOR SANITIZING INDUSTRIAL OR NON-FOOD CONTACT SURFACES SUCH AS EQUIPMENT FOR MIXING, PACKING, OR PACKAGING PRODUCTS, PRODUCT TRANSFER LINES, STORAGE TANKS, FLOORS, AND WALLS.
- USES NOT REGISTERED IN THE STATE OF CALIFORNIA: OIL PRODUCTION AND TRANSMISSION PIPELINES AND SYSTEMS, FRACTURING FLUIDS.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE

This product is incompatible with many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. The product can be stored and handled in baked phenolic -lined steel, polyethylene, stainless steel, or reinforced epoxy -plastic equipment. This product freezes at about -6°F (-21°C). Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage times (up to about 1 month), temperatures of up to 100 °F (37.8° C) can be tolerated but the preferred maximum storage temperature is about 80 °F (26.7 °C).

Handle in a well -ventilated area. If vapors are irritating to the nose or eyes, special ventilation or respiratory protection (MSHA/NIOSH approved air purifying respirator equipped with an organic vapor cartridge) may be required.

PESTICIDE DISPOSAL

Open dumping is prohibited. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or your Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING

Nonrefillable container. Do not reuse or refill this container. Triple or pressure rinse container (or equivalent) promptly after emptying.

(For containers 5 gallons or less)

Triple Rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

(For containers larger than 5 gallons)

Clean container promptly after emptying. Triple Rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times.

Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or other procedures approved by state and local authorities

Bionix GA50M (89110-TBD)

Isomeric Industries

A530 - September 13, 2016, Label Version (4), November 3, 2016

Page 3 of 4

WARRANTIES AND WARRANTY DISCLAIMERS

Conditions of Sale: Isomeric Industries ("ISOMERIC") warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in accordance with the directions under normal conditions of use. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal use conditions, or under conditions not reasonably foreseeable to ISOMERIC. To the extent consistent with applicable law, ISOMERIC DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY. To the extent consistent with applicable law, ISOMERIC SHALL NOT BE LIABLE FOR CONSEQUENTIAL, SPECIAL, OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, and ISOMERIC's sole liability and Buyer's and User's exclusive remedy shall be limited to the refund of the purchase price. BUYER AND USER ACKNOWLEDGE AND ASSUME ALL RISKS AND LIABILITY RESULTING FROM HANDLING, STORAGE AND USE OF THIS PRODUCT. ISOMERIC DOES NOT AUTHORIZE ANY AGENT OR REPRESENTATIVE TO MAKE ANY OTHER WARRANTY, GUARANTEE OR REPRESENTATION CONCERNING THIS PRODUCT.

Bionix GA50M (89110-TBD)

Isomeric Industries

A530 - September 13, 2016, Label Version (4), November 3, 2016

Page 4 of 4

Heffernan, Aline

From: Abigail Wacek <AWacek@tsgusa.com>
Sent: Thursday, November 03, 2016 7:56 PM
To: Heffernan, Aline
Subject: RE: 89110-G 100% Repack
Attachments: 89110-TBD.201609134.Bionix GA50M Clean.pdf; 89110-TBD.201609134.Bionix GA50M Redline.pdf

Aline,

Please see the revised label attached.

Thank you!

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

CONFIDENTIALITY NOTICE: This e-mail and any attachments contain information from Technology Sciences Group Inc., and are intended solely for the use of the named recipient or recipients. Any dissemination of this e-mail by anyone other than an intended recipient is strictly prohibited. If you are not a named recipient, you are prohibited from any further viewing of the e-mail or any attachments or from making any use of the e-mail or attachments. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments.

From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Tuesday, November 01, 2016 10:10
To: Abigail Wacek
Subject: RE: 89110-G 100% Repack

Abby,

I was looking over your label and the proposed changes look ok to me. One of the changes I mentioned earlier was adding not for food contact surfaces to the Animal Production Facilities directions. On [REDACTED], the directions clearly state not for food contact. Please revise the label to include this change.

Thank you,

Aline

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Tuesday, November 01, 2016 9:22 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: 89110-G 100% Repack

Aline,

Per our call we have removed "functional fluids" and clarified "water based conveyor lubricants" on page two of the label. Please see the redline and clean copies of the label attached. Please let me know if any additional changes are required at this time.

Thank you!

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

CONFIDENTIALITY NOTICE: This e-mail and any attachments contain information from Technology Sciences Group Inc., and are intended solely for the use of the named recipient or recipients. Any dissemination of this e-mail by anyone other than an intended recipient is strictly prohibited. If you are not a named recipient, you are prohibited from any further viewing of the e-mail or any attachments or from making any use of the e-mail or attachments. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments.

From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Friday, October 28, 2016 15:17
To: Abigail Wacek
Subject: RE: 89110-G 100% Repack

Abby,

Were you able to get into contact with your client about the requested changes to the label?

Aline

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Wednesday, October 19, 2016 9:49 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: 89110-G 100% Repack

Aline,

Let me speak with my client to get clarification on that use site. I will also tell them about the label revision. I do not anticipate that they will have any questions about that change.

Thanks,

Abby

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

CONFIDENTIALITY NOTICE: This e-mail and any attachments contain information from Technology Sciences Group Inc., and are intended solely for the use of the named recipient or recipients. Any dissemination of this e-mail by anyone other than an intended recipient is strictly prohibited. If you are not a named recipient, you are prohibited from any further viewing of the e-mail or any attachments or from making any use of the e-mail or attachments. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments.

From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Tuesday, October 18, 2016 15:52
To: Abigail Wacek
Subject: RE: 89110-G 100% Repack

Abby,

I looked over the label you sent and I have a few additional questions. It is unclear to me how functional fluids and lubricants are the same as aqueous metalworking fluids.

In the direction for animal production facilities and farm equipment could you add clearly non-food contact surfaces only or something to that effect. On [REDACTED], [REDACTED] To prevent any confusion it would be beneficial to have this statement on the label.

Thank you,

Aline

From: Abigail Wacek [<mailto:AWacek@tsgusa.com>]
Sent: Friday, October 14, 2016 11:10 AM
To: Heffernan, Aline <heffernan.aline@epa.gov>
Subject: RE: 89110-G 100% Repack

Aline,

Thank you for the call today. Per our call today please see the attached revised CSF with the [REDACTED] removed as an alternate supplier. This product was inadvertently included in the CSF but is not an MUP and so therefore not applicable to this formulation. I apologize for the error. Please also find the attached revised product label, clean and redline copies.

Per our discussion today I believe that the primary use sites of concern were the hatching eggs, function fluids and lubricants, and the oil well uses. Isomeric has removed the hatch eggs use site, see attached. The functional fluids and lubricants are a part of the larger aqueous metal working fluids and industrial processes and water systems, a use site which is found on [REDACTED] Lastly, the draft Isomeric label states oil well drilling, oil field processing applications, and oil field water systems. [REDACTED]

While the terminology is slightly different we believe that these use sites all fall under the same category. This is supported by the Industrial Processes and Water Systems use site in the RED which includes the following uses: oil-storage tanks; waterfloods; drilling muds, drilling, completion, and workover fluids; packer fluids; gas-production and transmission pipe systems; gas storage wells and systems; hydrotesting; pipeline pigging and scraping operations; paper mills and paper mill process water systems; pigments, filler slurries and water based coatings for paper and paperboard; metalworking fluids; water-based conveyor lubricants; air washer and industrial scrubbing; systems/recirculating cooling and process water systems; service water and auxiliary systems; heat transfer systems; industrial waste-water systems; and sugar beet mills and process water systems.

I hope that this has addressed your concerns. Please let me know if you have any questions or if any additional changes are needed. Thank you again for your call today.

Have a nice weekend!

Abigail T.D. Wacek | Regulatory Consultant
Technology Sciences Group Inc. (TSG)
1150 18th Street, NW, Suite 1000 | Washington, DC 20036
Tel: 202.828.8992 | Fax: 202.872.0745 | awacek@TSGUSA.com
Visit us at www.TSGUSA.com

CONFIDENTIALITY NOTICE: This e-mail and any attachments contain information from Technology Sciences Group Inc., and are intended solely for the use of the named recipient or recipients. Any dissemination of this e-mail by anyone other than an intended recipient is strictly prohibited. If you are not a named recipient, you are prohibited from any further viewing of the e-mail or any attachments or from making any use of the e-mail or attachments. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments.

From: Heffernan, Aline [<mailto:heffernan.aline@epa.gov>]
Sent: Friday, September 30, 2016 11:33
To: Abigail Wacek
Subject: 89110-G 100% Repack

Ms. Wacek,

I am working on your PRIA for 89110-G. Please refer to the guidance for a 100% repack. The new product's label may include **only** those use sites approved on the labels of **all** products being repackaged. Please revise the label and/or the CSFs and resubmit.

Thank you,

Aline Heffernan
Regulatory Management Branch 1
Antimicrobials Division
Office of Pesticide Programs
703-347-8602

CONFIDENTIALITY NOTICE: This e-mail and any attachments contain information from Technology Sciences Group Inc., and are intended solely for the use of the named recipient or recipients. Any dissemination of this e-mail by anyone other than an intended recipient is strictly prohibited. If you are not a named recipient, you are prohibited from any further viewing of the e-mail or any attachments or from making any use of the e-mail or attachments. If you believe you have received this e-mail in error, notify the sender immediately and permanently delete the e-mail, any attachments, and all copies thereof from any drives or storage media and destroy any printouts of the e-mail or attachments.

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 9/14/16

Experts In-Processing Signature: M.P. Date 9/14/16 Fee Paid: Yes

Division management contacted on issues No Yes Date

EPA Reg. Number: <u>89110-G</u>		EPA Receipt Date: <u>9/14/16</u>				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <u>No Inerts to review 100% Re-Pack</u>	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)					X
	Certificate and data matrix consistent					
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)					X
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with <u>PR Notice 86-5</u>					X
8	<u>Notice of Filing</u> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

* Documentation: (Pass / Fail)

- Request forms are complete

* Zvents: (Pass / Fail)

- no Zvents to review

- 100% Re-Pass

* PRN 113: (Pass / Fail)

- no studies submitted

JIC 4-27-16

* Overall Status: (Pass / Fail)

Technology Sciences Group Inc.

1150 18th Street, NW, Suite 1000

Washington, D.C. 20036

Direct: (202) 828-8992

Fax: (202) 872-0745

E-Mail: awacek@tsgusa.com

Abigail T. D. Wacek

Regulatory Consultant



September 13, 2016

Julie Chao

Antimicrobials Division (7504P)

Office of Pesticide Products

U.S. Environmental Protection Agency

Room 5-4900, One Potomac Yard

2777 South Crystal Drive

Arlington, VA 22202-4501

Submitted electronically

Re: A530-Application for a New Product: 100% Re-Package

Company Name: Isomeric Industries

Product Name: *BIONIX GA50M*

EPA Reg. No.: 89110-TBD

Dear Julie,

Technology Sciences Group, Inc., on behalf of Isomeric Industries, hereby submits the enclosed application to register *BIONIX GA50M*. This product is a 100% re-package of several identical 50% glutaraldehyde Manufacturing Use Product (MUP) registrations. Please find the following enclosed to support this application:

1. Application for Registration (EPA Form 8570-1);
2. Confidential Statement of Formula (EPA Form 8570-4) Basic and Alternate #1;
3. Formulator's Exemption (EPA Form 8570-27);
4. Product Label dated September 13, 2016;
5. PRIA category A530, Payment Confirmation Receipt, Pay.gov Tracking ID: 25TQK42V, Agency Tracking ID: 75089348174;
6. Small Business Waiver certification statement;
7. Letter of Authorization.

Please do not hesitate to contact me with any questions at (202) 828-8992 or via e-mail:

awacek@tsgusa.com.

Sincerely,

Abigail T.D. Wacek
Regulatory Consultant

Washington, D.C.

1150 18th St., NW, Suite 1000

Washington, D.C. 20036

Phone: (202) 223-4392

California

712 Fifth St., Suite A

Davis, CA 95616

Phone: (530) 757-1245

Canada

275 Slater St., Suite 900

Ottawa, Ontario K1P 5H9

Phone: (613) 247-6285

Abigail Wacek

From: notification@pay.gov
Sent: Saturday, September 10, 2016 16:29
To: Abigail Wacek
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25TQK42V
Agency Tracking ID: 75089348174
Transaction Type: Sale
Transaction Date: 09/10/2016 04:28:41 PM EDT

Account Holder Name: Chris A Harken

Transaction Amount: \$320.00
Card Type: AmericanExpress
Card Number: *****2005

Registration Number: 89110-TBD
Company Name: ISOMERIC INDUSTRIES INC.
Company Number: 89110
Action Code: A530

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Isomeric Industries 361 17th Street NW #1224 Atlanta, GA 30363	EPA File Symbol/Registration Number 89110-TBD
	Product Name BIONIX GA50M
	Date of Confidential Statement of Formula (EPA Form 8570-4) 09/13/2016

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Glutaraldehyde (43901)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

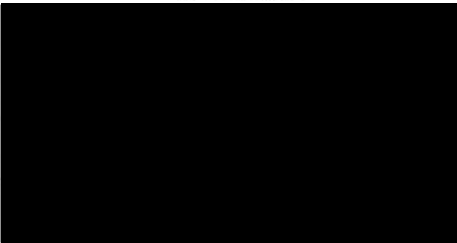

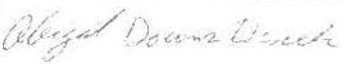

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Glutaraldehyde (43901)		
Signature 	Name and Title Abigail T. D. Wacek, Consultant 	Date 09/13/2016

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Please read instructions on reverse side before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

		United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I					
1. Company/Product Number 89110-TBD		2. EPA Product Manager Julie Chao		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Isomeric Industries / BIONIX GA50M		PM# 33			
5. Name And Address Of Applicant (Include ZIP Code) Isomeric Industries 361 17th Street NW #1224 Atlanta, GA 30363		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
<input type="checkbox"/> Check if this is a new address					
Section II					
<input type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below.		<input type="checkbox"/> Final Printed labels in response to Agency letter dated _____ <input checked="" type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain Below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) A530 100% re-pack application for a new manufacturing use product. A PRIA pre-payment has been made for this action and receipt included in this application (Pay.gov Tracking ID: Pay.gov Tracking ID: 25TQK42V, Agency Tracking ID: 75089348174.) Please confirm receipt and forward all communication to Abigail Wacek, Technology Sciences Group, 1150 18th Street, NW, Suite 1000, Washington, D.C. 20036 or awacek@tsqusa.com.					
Section III					
1. Material This Product Will Be Packaged In:					
Child Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. Container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(S) Retail Container 5 gal pail; 15, 30, 55 gal drum; 275, 330 gal tote bin, bulk tanker		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithographed <input type="checkbox"/> Pager glued <input type="checkbox"/> Stenciled <input checked="" type="checkbox"/> Other <u>Self adhesive</u>			
Section IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Abigail Wacek, Technology Sciences Group		Title Regulatory Consultant		Telephone No. (Include Area Code) 202-828-8992	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Consultant			
4. Typed Name Abigail T.D. Wacek		5. Date September 13, 2016			

